IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 05-590-GMS
v.	)	
	)	
DEXCOM, INC.,	)	
	)	
Defendant.	)	

DEXCOM, INC.'S REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS

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I. INTRODUCTION

The test in evaluating whether a declaratory judgment complaint satisfies the "case or controversy" requirement is whether the conflict is "real and immediate." *Lang v. Pacific Marine & Supply Co., Ltd.,* 895 F.2d 761, 764 (Fed. Cir. 1990). Subject matter jurisdiction analysis does not involve prediction of what "could very well" happen (quoting Abbott's declarant, Timothy Goodnow, at paragraph 5 of his Declaration). DexCom appreciates Abbott's confidence in the future FDA approval of its product, and of course, is optimistic itself that some day it will have a product composed in some manner which is approved by the FDA. Abbott's confidence in DexCom's ultimate success aside, Mr. Goodnow's position is the same as DexCom's on the fundamental issue: the timing of FDA approval and what is approved is not certain.

Every court since *Lang* that has faced this issue—a plaintiff seeking a declaration that defendant's yet-to-be-FDA-approved medical device *will* infringe—has dismissed the complaint for lack of jurisdiction. Abbott attempts to rely on a body of case law in which the infringing activity was the filing of an ANDA itself, a statutory mechanism under the Hatch-Waxman Act that "provided patentees with *a defined act of infringement sufficient to create case or controversy jurisdiction.* " *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (emphasis added). Abbott's cases are inapposite. Count I of Abbott's Complaint is premature, and the Court should dismiss it for lack of subject matter jurisdiction.

In Count II of its Complaint, Abbott fails to plead facts upon which relief could be granted. Patent infringement occurs where a party "makes, uses, offers to sell or sells" a patented invention. The patent laws do not impose liability for "displaying" an experimental device, indisputably developed for FDA clinical trials, that an aggressive plaintiff suspects might infringe once it is approved by the FDA. *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997). DexCom is prohibited from using or making available its device except for FDA-authorized purposes, which allow display at

a "trade show." Because DexCom has developed its experimental STS devices in this strictly regulated FDA context, the conduct alleged by Abbott—"displaying" the same device used for clinical trials at a "trade show"—is insulated from liability by Section 271(e)(1). Abbott's allegations are insufficient, and Count II should be dismissed.

There is only one aspect of Abbott's case that is certain. It is certain that Abbott will use its premature lawsuit to inflict business pain on DexCom, a startup company trying to obtain FDA approval of a medical device that will improve the lives of diabetes patients. Until it is certain that there is subject matter jurisdiction and a FDA approved product to fight over, there is no legal or policy basis for this Court's resources to be employed in support of such an endeavor.

II. ARGUMENT

A. ABBOTT'S COMPLAINT FOR DECLARATORY RELIEF IS PREMATURE AND SHOULD BE DISMISSED.

1. Abbott's Anticipated Conflict With DexCom Is Neither Real Nor Immediate.

In determining whether a patent holder's complaint under 28 U.S.C. § 2201 satisfies the Article III case-or-controversy requirement, the Federal Circuit has held that "*the sole requirement* for jurisdiction under the [Declaratory Judgment] Act is that the *conflict be real and immediate*, *i.e.,* that there be a true, actual 'controversy' required by the Act." *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.,* 982 F.2d 1520, 1526 (Fed. Cir. 1992) (emphasis added), quoting *Lang,* 895 F.2d at 764. If there is no actual controversy, a district court lacks jurisdiction to hear a claim for declaratory relief. That determination is made from the *facts* as they existed at the time Abbott filed its Complaint—August 11, 2005. *See Lang,* 895 F.2d at 764. Because it was uncertain on August 11, 2005, whether or when such a device will exist, Abbott's Complaint is premature and must be dismissed.

Contrary to Abbott's argument, DexCom has applied the correct test—quoted above from *Lang*—to determine whether jurisdiction exists. Each of the cases cited by

DexCom in its Opening brief (D.I. 6) was decided after *Lang* and applied the test set forth by the Federal Circuit therein. And each court has held that it lacked subject matter jurisdiction over claims for future patent infringement by yet-to-be-FDA-approved devices. *See, e.g., Telectronics,* 982 F.2d at 1527 (affirming district court's dismissal of declaratory judgment action as premature in light of ongoing FDA review of defendant's medical device); *NeoRx Corp. v. Immunomedics, Inc.,* 877 F. Supp. 202, 214 (D. N.J. 1994) (finding that patentee failed to make a sufficient allegation of immediacy and reality because it was unclear whether FDA would grant defendant's application for license to manufacture accused product); and *Intermedics, Inc. v. Ventritex, Inc.,* 775 F. Supp. 1269, 1289-90 (N.D. Cal. 1991) (dismissing declaratory judgment action as premature in light of ongoing FDA review of defendant's medical device) *aff'd*, 991 F.2d 808 (Fed. Cir. 1993).

In *Sierra Applied Sciences, Inc. v. Advanced Energy Indus., Inc.,* 363 F.3d 1361 (Fed. Cir. 2004), the Federal Circuit further explained its rationale in *Telectronics*:

> *Telectronics* implicitly tied the concept of "reality" to whether the design of the potentially-infringing subject of the declaratory-judgment suit was substantially *fixed*, particularly with respect to its potentially infringing characteristics, on the date the complaint was filed. Thus, in analyzing jurisdiction over a suit involving a medical device, *Telectronics* placed great weight on the fact that "[t]here was no certainty that the device when approved would be the same device that began clinical trials." 982 F.2d at 1527. This approach is proper: The greater the variability of the subject of the declaratory-judgment suit, particularly as to its potentially infringing features, the greater chance that the court's judgment will be purely advisory, detached from the eventual, actual content of that subject--in short, detached from eventual reality.

Sierra, 363 F.3d at 1379 (emphasis in original). Despite Abbott's confidence in its ability to predict the outcome of DexCom's FDA review, whether the FDA will approve the STS device is uncertain; when that approval might occur is uncertain; and what the final

components of an approved device would be is uncertain. Given that compound uncertainty, Abbott's anticipated dispute with DexCom is neither real nor immediate under the Federal Circuit's analysis in *Telectronics* and *Sierra*.

2. Abbott's "ANDA" Cases Are Inapposite; Under 35 U.S.C. § 271(e)(2), "Case Or Controversy" Jurisdiction Is Satisfied When Defendant Files The ANDA Itself

Abbott seeks a declaration of future infringement—*viz.*, a judicial declaration that DexCom's yet-to-be-FDA-approved STS device will infringe at least one claim of Abbott's patents. Abbott does not cite a single case in its Opposition, however, in which a court has exercised jurisdiction where a patentee seeks a declaration that a yet-to-be-FDA-approved medical device will infringe its patents. That is because no such case exists. In every published decision where a defendant has moved to dismiss for lack of subject matter jurisdiction because its accused device had not yet been approved by the FDA, the court either concluded it lacked jurisdiction or declined to exercise jurisdiction. *See, e.g., Telectronics Pacing Sys.*, 982 F.2d at 1527; *Intermedics*, 775 F. Supp. at 1289-90; *Intermedics, Inc. v. Ventritex, Inc.*, 991 F.2d 808 (Fed. Cir. 1993) (affirming dismissal); *NeoRx Corp.*, 877 F. Supp. at 214; *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112 (D. Mass. 1998) (noting that, even if the court had jurisdiction, the fact that the accused product had not yet been approved by FDA "militate[s] against exercising jurisdiction"). And in the most recent case addressing that same issue, the district court dismissed the plaintiffs' complaint for lack of jurisdiction. *Alphamed Pharms Corp. v. Arriva Pharms, Inc.*, No. 03-20078, 2005 WL 357326 at *8 (S.D. Fla. Jan. 5, 2005) (attached hereto as Ex. D) (determining that allegations of imminent FDA approval were merely speculative and that plaintiff was unable to allege facts that approval was real and imminent).

The facts and law compel the same outcome here.

In response to this line of cases directly on point, Abbott cites cases in which allegations of patent infringement were premised on the filing of Abbreviated New Drug

Applications ("ANDA's"). In Section II.A. of its Opposition, Abbott cites six cases (the only patent cases Abbott cites to support "case or controversy" jurisdiction) for the proposition that "FDA approval is not necessary for jurisdiction" over a declaratory judgment claim for patent infringement. Abbott's Opposition to DexCom's Motion to Dismiss, D.I. 17 ("Oppo.") at 13.[1] These are all ANDA cases, making them easily distinguishable and inapplicable.

The Hatch-Waxman Act, which authorized ANDAs, permits manufacturers of so-called "generic" drugs to market versions of patented drugs as soon as possible after the expiration of the relevant patent. Under that Act, a generic drug manufacturer may seek expedited approval to market a generic version of an already-approved drug by submitting an ANDA. In each of Abbott's six cases, plaintiffs alleged infringement under 35 U.S.C. § 271(e)(2). Section 271(e)(2) states that "[i]t shall be an act of infringement to submit . . . an application under section 505(j)[2] of the Federal Food, Drug and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A). Thus, in patent infringement cases brought under Section 271(e)(2), *the alleged infringing act is the filing of the ANDA itself.*

Abbott does not (and cannot) attempt to proceed against DexCom under Section 271(e)(2). Similarly, Abbott does not argue that DexCom's filing of its PMA application with the FDA is the alleged infringing act. Abbott seeks a declaration that DexCom's STS device, if approved, *will infringe* Abbott's four patents under 35 U.S.C. § 271(a) if and when DexCom "makes, uses or sells" its STS device in the United States. The

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[1] Those cases are *Glaxo Group Ltd. v. Apotex, Inc.,* 130 F. Supp. 2d 1006 (N.D. Ill. 2001); *Glaxo, Inc. v. Novopharm, Ltd.,* 110 F.3d 1562 (Fed. Cir. 1997); *Kos Pharm., Inc. v. Barr Labs, Inc.,* 242 F. Supp. 2d 311 (S.D.N.Y. 2003); *Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc.,* 329 F. Supp. 2d 394 (S.D.N.Y. 2004); *Astra Aktiebolag v. Andrx Pharms., Inc.,* 222 F. Supp. 2d 423 (S.D.N.Y. 2002); and *Glaxo, Inc. v. Torpharm, Inc.,* No. 95 C 4686, 1997 WL 282742, at *3 (N.D. Ill. May 18, 1997) (attached hereto as Ex. E). None of the other cases cited by Abbott to support its argument are patent cases, and none involve accused infringing devices that are under FDA review.

[2] 27 U.S.C. 505(j)(1) authorizes the filing of ANDA's.

difference in the alleged infringing acts—the filing of an ANDA (in Abbott's cases) versus "making, using or selling" an accused device in the future (in DexCom's cases)—is dispositive of the jurisdictional analysis. Abbott misapprehends this critical distinction in arguing that "no court has ever held that there is a special rule for medical device cases — in contrast to pharmaceutical cases — requiring FDA approval for jurisdiction." Oppo. at 13.

Congress created a special rule for pharmaceutical cases (i.e., ANDA cases) by enacting the Hatch-Waxman Act, which authorizes a patent infringement action in the generic pharmaceutical context, despite the absence of a real and immediate case or controversy. According to the Federal Circuit, "§ 271(e)(2) provided patentees with *a defined act of infringement sufficient to create case or controversy jurisdiction* to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (emphasis added). That "defined act of infringement" in pharmaceutical cases is the defendant's filing of the ANDA application itself. In each of the six ANDA cases cited by Abbott, the court properly exercised jurisdiction because the allegations (i.e., defendants filed an ANDA) satisfied the case and controversy requirement under Section 271(e)(2). *See id.* at 1571 ("The act of infringement that gives rise to a case or controversy under section 271(e)(2) has been stated to be 'artificial' . . .") *quoting Eli Lilly & Co. v. Medtronic,* 496 U.S. 661, 675 (1990). Because DexCom's accused STS device does not involve ANDA or allegations of infringement under Section 271(e)(2), Abbott's cases are inapposite.

Neither Congress nor the Federal Circuit has created an analogous "artificial" or "defined act of infringement" in non-ANDA cases, like here, where the accused medical device is in the midst of an uncertain and potentially lengthy FDA review process. *See, e.g., Telectronics Pacing Sys.,* 982 at 1527; *Intermedics,* 775 F. Supp. at 1289-90; *NeoRx Corp.*, 877 F. Supp. at 214; *Amgen,* 3 F. Supp. 2d at 112; and *Alphamed,* 2005 WL 357326 at *8. In each of those cases, the court dismissed the patentholder's declaratory

judgment claim accusing a yet-to-be-approved medical device due to lack of subject matter jurisdiction. Those cases, like this one, involve claims for future infringement, and they govern here. In this case, there must be a real and immediate case or controversy without any statutory help, and there is none.

3. Because FDA Approval Is Uncertain, Abbott's Claim For Future Infringement Is Not Ripe

Despite Abbott's speculative, unsupported statements that FDA approval of DexCom's STS device is "imminent" and a "foregone conclusion," it remains indisputable that whether and when DexCom's STS device will be approved are uncertain. Abbott's crystal ball[3] ignores or gives short shrift to the FDA's regulations and guidelines, the actions to date by the FDA, and Abbott's own experience with delays in the FDA review process for its continuous glucose monitor. Pointing to the FDA's decision to grant "expedited" review of DexCom's PMA application for the STS device, Abbott argues that FDA approval is a "foregone conclusion." Oppo. at 14. But that speculative assertion is contradicted by the very FDA publication Abbott cites. In its "Expedited Review of Premarket Submissions for Devices" (attached as Exhibit C to Abbott's Opposition), the FDA states that "[h]istorically, devices evaluated in accordance with expedited review procedures have not always shown reduced review times when compared to their non-expedited review counterparts." Abbott Oppo., Ex. C at 4.

Abbott knows that reality all too well. In its own March 12, 2004 10-K filing with the SEC, Abbott itself stated that FDA review of a PMA application "generally takes between one and three years, but may take significantly longer." (DexCom's Request For Judicial Notice In Support of Motion to Dismiss ("RJN, D.I. 7"), Ex. E at 11). Abbott filed its own PMA application for its continuous glucose monitoring device in November

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[3] Abbott's crystal ball comes in the form of a declaration from its Vice President of Research and Development (not its Vice President of Regulatory Affairs), Timothy Goodnow, who prognosticates (without any evidentiary support) that approval from the FDA is imminent. D.I. 18. Goodnow's declaration is rank speculation and should be disregarded. Moreover, Goodnow's statements are flatly contradicted by the FDA's own guidelines.

2003, and Abbott's device (like DexCom's) was granted expedited review by the FDA. *Id.* Expedited review, however, has not translated into "imminent" FDA approval for Abbott. Almost two years later, the FDA has yet to approve Abbott's device. Indeed, TheraSense/Abbott's PMA application for its Navigator system was further along in the FDA review process (than DexCom's currently is) when the FDA required additional clinical trials. (RJN, Ex. E at 30, 31).[4]

FDA approval is far from "imminent" or a "foregone conclusion" in light of the FDA's July 2005 "Major Deficiency Letter" requesting that DexCom submit additional information to the FDA as part of the review of the PMA application for the STS system. (*See* July 25, 2005 press release, attached hereto as Ex. A). In each of its public disclosures, DexCom has emphasized that the timing of FDA approval is uncertain, and that approval may not come at all. Abbott misleads the Court when it states that DexCom has "repeatedly stated that [additional] clinical trials would not be necessary." Oppo. at 15. For that false assertion, Abbott cites to page 9 of an uncertified transcript of what purports to be a speech delivered by DexCom's CEO, Andrew Rasdal. (Oppo. at Ex. F). A review of that transcript, however, reveals that Mr. Rasdal never made such a statement.

On September 12, 2005, DexCom announced publicly that it had submitted its response to the FDA's request for additional information. (*See* September 12, 2005 press release, attached hereto as Ex. B). The FDA has not told DexCom, as Abbott suggests, that no further clinical trials will be required going forward. The FDA did not require additional clinical trials *during or after* the "100-day" meeting with DexCom, but nothing precludes the FDA from requesting data from additional clinical trials as a condition of

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[4] Abbott tries to avoid the comparison of its own FDA experience with that of DexCom by suggesting that DexCom "reportedly" is seeking approval for its STS system under a so-called "less rigorous" review process (adjunct labeling). Mr. Goodnow and Abbott fail to cite an FDA regulation (or any authority), however, for the statement that the FDA review process for "adjunct labeling" is less rigorous.

approval. As Abbott knows from its own experience, "achieving a completed application is a process that *may take numerous clinical trials* and require the filing of amendments over time." (Ex. E to RJN at 31) (emphasis added). Abbott's prognostications notwithstanding, FDA approval of DexCom's STS system is neither "imminent" nor a "foregone conclusion." Abbott's FDA problems with its continuous glucose monitoring system prove that FDA approval of STS is difficult and unpredictable.

There is no "real and immediate" case or controversy. There is only a real and immediate prospect that this Court's "judgment will be purely advisory" and "detached from . . . eventual" reality. *See Sierra*, 363 F.3d at 1379.

B. DEXCOM'S DEVELOPMENT AND DISPLAY OF ITS DEVICE ARE INDISPUTABLY IN THE CONTEXT OF OBTAINING FDA APPROVAL AND ARE EXEMPT FROM INFRINGEMENT UNDER 35 USC 271(E)(1)

Abbott makes much of the exhibits and employee affidavit DexCom included with its moving papers, arguing that DexCom "ignores the relevant standard" for Rule 12(b)(6) motions. As DexCom stated in its moving papers, it was placing no reliance on the employee declaration, which DexCom provided solely should the Court wish to consider further factual details. Furthermore, the accuracy of the DexCom declaration has not been challenged by Abbott.

The documents submitted by DexCom—all of which are properly subject to judicial notice—do not convert DexCom's motion to dismiss into one for summary judgment under Fed.R.Civ.P. 56. The basis for DexCom's motion to dismiss Count II of Abbott's Complaint boils down to this: Abbott has not adequately pleaded a patent infringement claim based on DexCom's alleged trade show activity. Fully accepting the allegations in the Complaint, the Court should dismiss Abbott's "trade show" infringement allegation [Count II] as insufficient on its face.

Patent infringement occurs where a party "makes, uses, offers to sell or sells" a patented invention during the patent term and without the patent holder's authorization.

35 U.S.C. § 271(a). Section 271(e)(1) insulates a defendant from liability based on activity that would *otherwise* constitute infringement where the activity is directed toward experimental use or testing related to obtaining FDA approval.[5] "Thus, *a defendant need not show that all of its conduct falls under the section 271(e)(1) exemption, only the making, using, or selling of the claimed invention.* All other conduct falls outside the section 271(a) definition of infringement in the first instance." *Amgen,* 3 F. Supp. 2d at 107 (emphasis added).

In its Complaint (D.I. 1), Abbott does not accuse DexCom of having "used" its invention at the so-called trade shows; nor does Abbott accuse DexCom of having "sold" or "offered to sell" an infringing product at those two shows. Abbott does not and could not base its infringement claim on its assertion that DexCom "displayed" its prototype at conferences, because "displaying" is not an infringing activity under section 271(a). Instead, Abbott alleges that "DexCom's manufacture" of those products constitutes an infringing act (Compl. ¶ 28), and that DexCom's "manufacture", which would otherwise be exempt under 271(e)(1), is not exempt because the product was made—according to Abbott's allegation pled only on "information and belief"—"for the purpose of showcasing it at trade shows." *Id.*

In 1984, Congress enacted section 271(e)(1) in part to allow inventors to pursue regulatory approval without fear of infringement litigation. *See, e.g., Nexell Therapeutics, Inc. v. Amcell Corp.*, 143 F. Supp. 2d 407, 419 (D. Del. 2001) (McKelvie, J.). To this end, the phrase "reasonably related" must be broadly construed, because the information ultimately required for FDA approval will not always be predictable. *See Nexell*, 199 F. Supp. 2d 197, 205 (D. Del. 2002) (quoting *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991)). In *Telectronics*, the Federal Circuit found that a medical conference demonstration for the purpose of clinical investigator recruitment was

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[5] As DexCom noted in its Opening Brief, the Supreme Court has held that this provision also applies to medical devices. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 673-74 (1990).

an activity reasonably related to FDA approval. *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992). DexCom's "display" activity is legally indistinguishable from the demonstration in *Telectronics*, and is therefore reasonably related to FDA approval as well.

Abbott suggests that DexCom must be misleading the Court about its motives for making the experimental devices displayed at the trade shows, because the FDA has not presently asked DexCom for additional data. This argument fails on its face, because the FDA is authorized to request additional clinical data at any time prior to approval. *See, e.g.*, 21 C.F.R. § 812.30(b)(3).

Even if Abbott's allegation—that DexCom's display of its STS system was nothing more than an attempt to "generate buzz" under the guise of recruiting clinical investigators for FDA trials—were true, Abbott does not allege in its Complaint that this was DexCom's *sole* reason for manufacturing its devices. The Federal Circuit has made it very clear on more than one occasion that alternative non-infringing uses do not take an activity outside section 271(e)(1)'s protective shield once a reasonable relation to FDA approval is established. "The statute . . . does not look to the underlying purposes or attendant consequences of the activity…as long as the use is reasonably related to FDA approval. In other words, the statutory language allows [defendant] to use its data from the tests for more than FDA approval." *Abtox, Inc, v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997); *see also Telectronics*, 982 F.2d at 1525 ("If Congress intended to make [immediate competition at the end of the patent term] more difficult, if not impossible, by preventing competitors from using, in an admittedly non-infringing manner, the derived test data for fund raising and other business purposes, it would have made that intent clear."). If DexCom's alleged infringing activity – i.e. manufacturing its experimental device – was for uses reasonably related to FDA approval, then the resulting product can also be used for more than FDA approval – i.e. displaying the device at conferences.

Abbott's insistence (in defense of Count I) that DexCom is aggressively moving its FDA application forward concedes that DexCom at least concurrently manufactured its experimental device for testing and FDA-related purposes. Conspicuously absent from Abbott's Complaint is an allegation that DexCom *did not* manufacture its STS devices for the purpose of gathering information to submit to the FDA. Instead, Abbott's sole allegation on this point (made upon information and belief) ambiguously pleads that DexCom's *primary subjective purpose* was to "showcase" them at the trade shows ("the products displayed at the trade shows were manufactured for the purpose of showcasing at the trade shows *rather than* for the purpose of gathering information for submission to the FDA.") (Complaint at ¶ 17) (emphasis added). No matter how one construes Abbott's ambiguous allegation, Count II is hopelessly flawed. Displaying an allegedly infringing device does not infringe a patent, no matter what the underlying purpose. And, even if DexCom did "make" its experimental device "for the purpose of showcasing it at trade shows," it is undisputed that the device was used for clinical trials. The case law interpreting Section 271(e)(1) places DexCom's allegedly dual-purpose activity squarely within the statutory exemption.

As long as the *making* of the product is reasonably related to FDA approval, it does not matter if the product is ultimately put to other non-infringing uses.[6] "The phrase 'solely for uses reasonably related' is not equivalent to the phrase 'use is solely for purposes reasonably related.'...Uses... may be related to FDA approval, and yet be conducted for purposes other than, or in addition to, obtaining FDA approval." *Amgen*, 3 F. Supp. 2d at 107. As long as DexCom made its device for uses reasonably related to

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[6] Abbott implies that DexCom deviously omitted reference to the Supreme Court's holding in *Merck KGaA v. Integra Lifesciences I, Ltd*, 125 S. Ct. 2372 (2005). (Oppo. at 5.) However, the holding Abbott attributes to *Merck* is inapplicable to the instant analysis. The factual question of whether certain experiments will generate data that is relevant to FDA approval does not exist here, where the only activity that must be relevant to FDA approval is DexCom's manufacture of its product.

FDA approval, *e.g.* clinical testing, it does not matter if DexCom also "create[d] a buzz" by displaying it to the public.

Assuming *arguendo* that DexCom did "make" its device in order to display it at conferences, this would not remove a device used for clinical trials from the protection of section 271(e)(1).

Abbott does not dispute that DexCom manufactured samples of its product in order to conduct clinical testing and obtain FDA approval. D*isplay* of such devices does not eliminate the protection of Section 271(e)(1), as a matter of law.

C. EVEN IF "CASE AND CONTROVERSY" JURISDICTION IS PRESENT, THE COURT SHOULD DECLINE TO EXERCISE JURISDICTION

Finally, even if jurisdiction does exist (and it does not), the Court should decline to exercise jurisdiction for important policy reasons. *See Minnesota Mining & Mfg. Co. v. Norton Co.,* 929 F.2d 670, 672 (Fed. Cir. 1991) (even if plaintiff alleges facts sufficient such that justiciable controversy exists, court has discretion to decline the declaratory judgment jurisdiction).

"Subjecting [DexCom] to an infringement litigation at present may run afoul of the Congressional policy underlying the section 271(e)(1) exemption." *Amgen*, 3 F. Supp. 3d at 112; *Intermedics,* 775 F. Supp. at 1290 (same). In *Intermedics,* the district court declined to exercise jurisdiction in light of the chilling effect such lawsuits can have among competitors: "At least for relatively small start-up companies . . . where much of the business and technical work essential to survival is done by a small group of people, the promise by Congress of a safe haven could prove illusory if the courts permitted competitors to proceed full-bore with expensive, resource-draining, and personnel-distracting litigation in the form of actions for declaratory relief." 775 F. Supp. at 1290. As the court concluded, "[i]t makes little sense, and thus we assume would be inconsistent with Congress' intent, to protect companies . . . from suit for actual patent infringement but leave them fully exposed to declaratory relief actions whose gravamen

and burdens are much the same." *Id.* Permitting Abbott to jump the gun raises these same concerns. Large companies (like Abbott) could stifle competition from new, development-stage companies (like DexCom) by filing a premature complaint for declaratory relief during the arduous FDA approval process in the certainty that the premature filing will at a minimum harass the new competitor and cause uncertainty among investors.

Abbott's Complaint seeks an advisory opinion from this Court. Despite Abbott's statements to the contrary, the FDA review process *is* uncertain. It is uncertain whether the STS device will be approved by the FDA, and whether it will possess the same features it currently incorporates. A patent infringement analysis requires comparing the construed claims of the patents against the features of the accused device. Here, because FDA review of DexCom's STS glucose monitoring system is ongoing and the outcome uncertain, there is no "accused product" for the Court to compare against the construed claims of the four Abbott patents. Even if the Court and the parties were to begin that analysis using the current embodiment of the STS system, the time and resources expended would be wasted if material features of the device change prior to FDA approval. *See Sierra*, 363 F.3d at 1379 ("The greater the variability of the subject of a declaratory-judgment suit, particularly as to its potentially infringing features, the greater chance the court's judgment will be purely advisory.").

That Abbott is asking for an advisory opinion is a particular concern given that civil cases in this Court proceed from filing to trial in approximately 24 months. (*See* Excerpt from 2003 Annual Report of Administrative Office of the United States Courts, attached as Ex. C) (of which this Court can take judicial notice). As Abbott has recognized, FDA review of a PMA application "generally takes between one and three years, but may take significantly longer." (Ex. E to RJN, at 11). DexCom filed its application for PMA review in March of 2005. Approval of its system, applying

Abbott's "one to three year" estimate for FDA approval, could come as late as March 2008.

If the Court were to deny DexCom's motion and this case were to proceed, FDA review may not even be complete before this matter is tried to verdict. If the device ultimately were not approved, or were to emerge from the FDA review process with material modifications, both the Court and DexCom will have wasted considerable time and financial resources on a moot dispute. Only Abbott's investment would not be wasted because it would have accomplished its business objective of imposing "expensive, resource-draining, and personnel-distracting litigation" on DexCom. *Intermedics*, 775 F.Supp. at 1290.

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CERTIFICATE OF SERVICE

I hereby certify that on the 29th day of September, 2005, the attached **DEXCOM, INC.'S REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS** was served upon the below-named counsel of record at the address and in the manner indicated:

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/s/ John G. Day

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